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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,335	09/02/2004	Eiko Kato	Q68931	8830

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EXAMINER	
GULLEDGE, BRIAN M	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
11/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/506,335	KATO ET AL.	
	Examiner	Art Unit	
	Brian Gulledge	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 2, 2009 has been entered.

Previous Rejections

Applicants' arguments, filed October 2, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Duplicate Claims

Applicant is advised that should claim 18 be found allowable, claim 19 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-17 stand rejected and claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. (*Free Rad. & Med.*, 1997, 22(5), pages 761-769) in view of Takata et al. (*J. Pharm. Sci.*, 1995, 84(1), pages 96-100) and Yasuaki (JP 62-106005). Applicant argues that the rejection is not proper as Takata et al. only discloses analysis of kinetics if hydrolysis, and does not teach or suggest a method of applying a whitening cosmetic composition to the skin like the present invention. The Applicant also argues that the rejection is not proper due to the unexpectedly superior results, as demonstrated by the evidence present in the declaration filed under 37 CFR 1.132.

The Examiner is not persuaded by these arguments. The Examiner did not rely on the teaching of Tanaka et al. alone, but rather the combination of the teachings of the above references. There is no requirement that each reference relied upon in a 103 rejection teach all of the limitations of the claims, but rather the combined teaches read upon and render prima facie obvious the recited invention. As for the declaration, the evidence supplied was not found persuasive (see the discussion below).

Claims 15-17 stand rejected and claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke et al. (*Nutrition and Cancer*, 2000, 38(1), pages 87-97) in view of Takata et al. (*J. Pharm. Sci.*, 1995, 84(1), pages 96-100). Applicant argues that the rejection is not proper as Takata et al. only discloses analysis of kinetics if hydrolysis, and does

not teach or suggest a method of applying a whitening cosmetic composition to the skin like the present invention. The Applicant also argues that the rejection is not proper due to the unexpectedly superior results, as demonstrated by the evidence present in the declaration filed under 37 CFR 1.132.

The Examiner is not persuaded by these arguments. The Examiner did not rely on the teaching of Tanaka et al. alone, but rather the combination of the teachings of the above references. There is no requirement that each reference relied upon in a 103 rejection teach all of the limitations of the claims, but rather the combined teaches read upon and render prima facie obvious the recited invention. As for the declaration, the evidence supplied was not found persuasive (see the discussion below).

Declaration Filed Under 37 CFR 1.132

The declaration filed under 37 CFR 1.132 filed October 4, 2009 is acknowledged and found insufficient to overcome the rejection of claims 15-26. The data provided in the declaration measures the effect of various lotions on reducing pigmentation in skin by applying the lotion to the skin after UV exposure. The instant specification also presents data with respect to lotions (lotions 1-12) and the effect these lotions had on reducing pigmentation of skin when applied to the skin after UV exposure. The data in the specification demonstrate that Lotions 1-4, which comprised d,l-α-, d-α-, d-γ-, and d-δ-tocopherol dimethylglycine ester hydrochlorides in 2.0 wt%, were effective at reducing pigmentation. The data presented in the declaration demonstrates that the corresponding lotions with d,l-α-, d,l-γ-, d,l-δ-tocopherol, and tocopherol-acetate were not effective.

This data does demonstrate that lotions with 2.0 wt% of d,l-α-, d-α-, d-γ-, and d-δ-tocopherol dimethylglycine ester hydrochloride reduces pigmentation of skin when applied to the skin after UV exposure. This particular effect is not expected. However, the Applicant argues that the data presented demonstrates that the compounds are superior with regards to the prevention of pigmentation. This has not been shown. The claims do not recite the reduction or elimination of pigmentation by applying the compound to the skin after UV exposure, but recite the broader use of simply accomplishing the effect by applying to the skin. The data do not provide comparative data when the lotion is applied before UV exposure. And one of ordinary skill in the art would have known that tocopherols lower pigmentation of skin when applied before UV exposure.[1]

Even if *en arguendo* unexpectedness has been established, the probative value of the evidence as compared to the invention as claimed must be determined, i.e., claims must be "commensurate in scope" with the showing. See MPEP 716.02(d). That is not the case with the instant claims. The claims are drawn to methods that encompass reducing or eliminating pigmentation by applying the composition to the skin. The data do not demonstrate eliminating pigmentation, nor does the data provided demonstrate an unexpected effect with regards to reducing pigmentation when the composition is applied before UV exposure. Claim 15-22 and 26 also encompass in their scope tocopherol esters other than tocopherol dimethylglycine ester hydrochlorides, which are the only species of tocopherol esters demonstrated to have the activity of reducing skin pigmentation by being applied after UV exposure. Additionally, lotions 7-10 (instant specification) had only 0.1 wt% of the tocopherol dimethylglycine ester hydrochlorides,

[1] Burke et al., Figure 1. This reference is not being used substantively as part of the rejection over Weber et al.,

and it is not clear if these lotions had an effect that was different from just tocopherol (compare with lotion b. provided in the declaration), which appears to not be active. And none of the claims are limited in scope to amounts of the tocopherol esters that are commensurate in scope with the data provided.

Conclusion

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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Takata et al., and Yasuaki, but rather only to demonstrate what the ordinary artisan would have expected at the time the invention was made.

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612